

EXHIBIT A

Manual of PATENT EXAMINING PROCEDURE

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2105 Patentable Subject Matter — Living Subject Matter [R-1]

The decision of the Supreme Court in *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980), held that microorganisms produced by genetic engineering are not excluded from patent protection by 35 U.S.C. 101. It is clear from the Supreme Court decision and opinion that the question of whether or not an invention embraces living matter is irrelevant to the issue of patentability. The test set down by the Court for patentable subject matter in this area is whether the living matter is the result of human intervention.

In view of this decision, the Office has issued these guidelines as to how 35 U.S.C. 101 will be interpreted.

The Supreme Court made the following points in the *Chakrabarty* opinion:

1. "Guided by these canons of construction, this Court has read the term 'manufacture' in § 101 in accordance with its dictionary definition to mean 'the production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties, or combinations whether by hand labor or by machinery.'"

2. "In choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope."

3. "The Act embodied Jefferson's philosophy that 'ingenuity should receive a liberal encouragement.' 5 Writings of Thomas Jefferson, at 75-76. See *Graham v. John Deere Co.*, 383 U.S. 1, 7-10 (1966). Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language. In 1952, when the patent laws were recodified, Congress replaced the word 'art' with 'process,' but otherwise left Jefferson's language intact. The Committee Reports accompanying the 1952 act inform us that Congress intended statutory subject matter to 'include any thing under the sun that is made by man.' S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952)."

4. "This is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature,

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1656 (Fed. Cir. 2004)(holding that a drawing made by an engineer that was not prior art may nonetheless “be used to demonstrate a motivation to combine implicit in the knowledge of one of ordinary skill in the art”).

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II. < SPECIFYING A PARTICULAR LEVEL OF SKILL IS NOT NECESSARY WHERE THE PRIOR ART ITSELF REFLECTS AN APPROPRIATE LEVEL

If the only facts of record pertaining to the level of skill in the art are found within the prior art of record, the court has held that an invention may be held to have been obvious without a specific finding of a particular level of skill where the prior art itself reflects an appropriate level. *Chore-Time Equipment, Inc. v. Cumberland Corp.*, 713 F.2d 774, 218 USPQ 673 (Fed. Cir. 1983). See also *Okajima v. Bourdeau*, 261 F.3d 1350, 1355, 59 USPQ2d 1795, 1797 (Fed. Cir. 2001).

>

III. < ASCERTAINING LEVEL OF ORDINARY SKILL IS NECESSARY TO MAINTAIN OBJECTIVITY

“The importance of resolving the level of ordinary skill in the art lies in the necessity of maintaining objectivity in the obviousness inquiry.” *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718, 21 USPQ2d 1053, 1057 (Fed. Cir. 1991). The examiner must ascertain what would have been obvious to one of ordinary skill in the art at the time the invention was made, and not to the inventor, a judge, a layman, those skilled in remote arts, or to geniuses in the art at hand. *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 218 USPQ 865 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1043 (1984).

2142 Legal Concept of *Prima Facie* Obviousness [R-6]

The legal concept of *prima facie* obviousness is a procedural tool of examination which applies broadly to all arts. It allocates who has the burden of going forward with production of evidence in each step of the examination process. See *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972); *In re Saun-*

ders, 444 F.2d 599, 170 USPQ 213 (CCPA 1971); *In re Tiffin*, 443 F.2d 394, 170 USPQ 88 (CCPA 1971), *amended*, 448 F.2d 791, 171 USPQ 294 (CCPA 1971); *In re Warner*, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968). The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. If, however, the examiner does produce a *prima facie* case, the burden of coming forward with evidence or arguments shifts to the applicant who may submit additional evidence of nonobviousness, such as comparative test data showing that the claimed invention possesses improved properties not expected by the prior art. The initial evaluation of *prima facie* obviousness thus relieves both the examiner and applicant from evaluating evidence beyond the prior art and the evidence in the specification as filed until the art has been shown to *>render obvious< the claimed invention.

To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical “person of ordinary skill in the art” when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention “as a whole” would have been obvious at that time to that person. Knowledge of applicant’s disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the “differences,” conduct the search and evaluate the “subject matter as a whole” of the invention. The tendency to resort to “hindsight” based upon applicant’s disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

ESTABLISHING A *PRIMA FACIE* CASE OF OBVIOUSNESS

**>The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396

(2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval). <

If the examiner determines there is factual support for rejecting the claimed invention under 35 U.S.C. 103, the examiner must then consider any evidence supporting the patentability of the claimed invention, such as any evidence in the specification or any other evidence submitted by the applicant. The ultimate determination of patentability is based on the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). The legal standard of "a preponderance of evidence" requires the evidence to be more convincing than the evidence which is offered in opposition to it. With regard to rejections under 35 U.S.C. 103, the examiner must provide evidence which as a whole shows that the legal determination sought to be proved (i.e., the reference teachings establish a *prima facie* case of obviousness) is more probable than not.

When an applicant submits evidence, whether in the specification as originally filed or in reply to a rejection, the examiner must reconsider the patentability of the claimed invention. The decision on patentability must be made based upon consideration of all the evidence, including the evidence submitted by the examiner and the evidence submitted by the applicant. A decision to make or maintain a rejection in the face of all the evidence must show that it was based on the totality of the evidence. Facts established by rebuttal evidence must be evaluated along with the facts on which the conclusion of obviousness was reached, not against the conclusion itself. *In re Eli Lilly & Co.*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990).

See *In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984) for a discussion of the proper roles of the examiner's *prima facie* case and applicant's rebut-

tal evidence in the final determination of obviousness. See MPEP § 706.02(j) for a discussion of the proper contents of a rejection under 35 U.S.C. 103.

2143 >Examples of< Basic Requirements of a *Prima Facie* Case of Obviousness

****>**The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1395-97 (2007) identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in *Graham*. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.

EXEMPLARY RATIONALES

Exemplary rationales that may support a conclusion of obviousness include:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.